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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,319	04/22/2005	Ellen J Baron	222310-US	9127

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,319	BARON ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0808*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2008 has been entered.

2. Claim 1 has been amended and claims 2-3 have been canceled. Accordingly, claims 1, 5 and 6 are now under consideration. Any rejections and/or objections not reiterated in the action have been withdrawn. It is also noted that applicant's remarks of August 28, 2008 have been considered, but are moot in view of the amendment of applicants' claims and the new grounds of rejection set forth below.

3. Receipt is acknowledged of the foreign priority documents filed August 28, 2008. The Office regrets any inconvenience caused to applicants in requiring the resubmission of the documents.

Information Disclosure Statement

4. It is noted that the new information disclosure statement filed August 28, 2008 is complete and has been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites the limitation "a the 16S/23S rDNA spacer region" in line 7. There is insufficient antecedent basis for this limitation in the claim, as the claim does not previously refer to a 16S/23S rDNA spacer region that might constitute "the 16S/23S rDNA spacer" referenced in the claim. As the recitation "a the" appears to be a typographical error, it is suggested that the claim simply be amended to delete "the". Claims 5-6 are considered indefinite because they depend from claim 1.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cockerill et al (US 7,074,598 B2 [11 July 2006; filed 25 September 2002]) in view of Tyrell et al (Journal of Clinical Microbiology 35(5):1054-1060 [May 1997]).

Cockerill et al disclose methods of detecting vancomycin-resistant *enterococci* in biological samples, which methods employ real time PCR (see entire reference, particularly, e.g., col 1, line 27-col 2, line 14; col 5, lines 3-34; and col 11, line 34-col 14, line 55). Cockerill et al disclose the analysis by their methods of samples including "anal or peri-rectal swabs, stool samples, blood, and body fluids" (see col 2, lines 66-67). Further, in detecting and determining the type of vancomycin-resistant enterococci present in such samples, Cockerill et al achieve the objective of "detecting the presence of a bacterial pathogen in a clinical sample," as set forth in the preamble of independent claim 1. Cockerill et al disclose the analysis of both samples and nucleic acids extracted therefrom, including total RNA or DNA extracted from clinical samples (see, e.g., col 9, lines 16-30), and therefore disclose "at least partially isolating nucleic acid" as set forth in the first step of claim 1. Cockerill et al disclose real-time PCR that is monitored by analysis of hybridization probe melting temperatures, allowing the identity of the specific target sequences present to be both detected and quantitated (see, e.g., col 12, line 59-col 14, line 55); therefore, Cockerill et al teach a "quantifying" step meeting the requirements of the claims with the exception of the identity of the target nucleic acid. Cockerill et al also exemplify the practice of their method (see, e.g., Example 3), and disclose that that samples with positive signals at melting temperatures corresponding to the various positive controls employed allow determination of the

presence of the target sequence indicated by the corresponding positive control, while samples having melting curves that are "not above baseline" are considered negative (see, e.g. col 20, lines 27-40). Thus, Cockerill et al inherently disclose that positive signals must exceed a certain level (i.e., a type of cut off value) to be considered positive, and that signals below baseline are considered negative. It is noted that the claims do not require, e.g., any particular steps of determining cut-off values prior to making comparisons, and that a comparison with a baseline value, as taught by Cockerill et al, could not be conducted if a baseline value has not been determined prior to the comparison; accordingly, Cockerill et al inherently teaches a cutoff value that is "predetermined." It is also noted that the claims recite the use of three different cutoff criteria only in the alternative; more particularly, the claims merely require determining whether an amount of nucleic acid is above a value, below a value, OR between two values; thus, the teachings of Cockerill et al meet the requirements of the claims as written. With further regard to claims 5 and 6, it is again noted that Cockerill et al disclose the analysis of blood, and the analysis of *enterococci*, as set forth above.

Cockerill et al do not teach methods in which the 16S/23S spacer region is employed as an amplification/detection target, as required by the claims.

Tyrell et al disclose methods in which PCR amplification of the enterococcal 16S/23S spacer region is employed to detect enterococci, teaching that the method is "a reliable technique for species identification of enterococci" (see entire reference, particularly the abstract). In view of the teachings of Tyrell et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

to have modified the method of Cockerill et al so as to have adapted the method to permit rapid species identification of enterococci via real time, specific PCR amplification of 16S/23S spacer sequences, either in addition to or instead of the *van* target sequences exemplified by Cockerill et al. An ordinary artisan would have been motivated to have made such a modification for the advantage of and in order to have achieved the predictable result of determining the species of enterococcus responsible for a particular infection, either instead of or in addition to determining whether the bacteria was vancomycin resistant. It is notice that the practice of such a method would result in a method in which "monitoring temperature dependence of hybridization indicates the presence of a group of predetermined species of said bacteria pathogen," as set forth in claim 1. It is further noted that as Tyrell et al disclose the sequences differences in the 16S/23S spacer region that characterize various enterococcal species, an ordinary artisan would have had a reasonable expectation of success in performing such methods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634

Diana B. Johannsen
Primary Examiner
Art Unit 1634